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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,535	02/09/2006	Edward Zbygniew Nowak	061170-0169 (JUSK-121)	3958

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EXAMINER	
SUTTON, DARRYL C	
ART UNIT	**PAPER NUMBER**
1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,535	NOWAK, EDWARD ZBYGNIEW	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) *16,17 and 19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/02/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of the election of Group I in the reply filed on 04/01/2009 is acknowledged. The traversal is on the ground(s) that the restriction is erroneous and therefore the requirement is improper. And, at the least Groups IV and V be joined with Group I for prosecution. This is not found persuasive because as cited by the Examiner, Group I is limited to a non-gelatin polymeric film, whereas Group IV is limited to a method of treatment of a non-gelatin polymeric film. A non-gelatin polymeric film is treated by the process of Group IV, but the treatment is not specifically adapted for the manufacture of the film since the film already exists. Group V is limited to a delivery capsule and does not have the limitation of a non-gelatin film.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 2, 3, 49, 10 and 13 are objected to because of the following informalities: The names of the polymers, HPMC, MHEC, HEC, EHEC, EC and MC should be included the first time that they are disclosed in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 7, 9, 12, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Eichel et al. (EP 0 391 518).

Eichel et al. teaches a sustained-release pharmaceutical preparation comprising a multi-walled coated drug comprised of a core, an inner wall layered with a solid acid, and an outer wall (Abstract, page 3, lines 54-58). The acid is neutralized by the by digestive fluids, subsequently the intestinal fluid diffuses into the capsule; the length of time for the delay of drug release is controlled by the amount of acid present (page 4, lines 1-5). The inner wall is preferably a cellulose acetate phthalate (page 9-20). The acid is selected from the group comprising citric acid, adipic acid and lactic acid (page 4, lines 21-25). The outer wall is selected from the group consisting of methacrylic acid ester copolymers and ethyl cellulose (page 4, lines 26-27). The acid is included in the enteric coating, i.e the inner coating, ranging from about 0-50% of the total weight of the coat, resulting in a layer of approximately 5 to 200 microns thickness; and alternatively, the coating level for the acid layer is preferably about 0 to about 50% the (page 4, lines 40-44). Example VI, the inner wall is comprised of a non-gelatin polymer, i.e. Eudragit^{R} L30D, and 10.5% of citric acid and is 40 microns thick.

The prior art anticipates the instant claims insofar as it discloses a non-gelatin film composition comprised of a non-gelatin polymer and a composition comprised of an organic acid; where the organic acid are carboxylic acids citric acid, adipic acid and lactic acid; and a film composition comprised of a non-gelatin polymer and 10.5% of citric acid which is 40 microns thick.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Signorino (WO 1992/11002).

Singnorino teaches a film forming composition for use in capsules consisting essentially of powdered pigment particles, a film-forming, edible polymer and up to approximately 30% water (Abstract). The film forming polymer is hydroxypropylmethyl cellulose (page 7, lines 1-2). The dispersing agent such as citric acid, malic acid, lactic acid are include in amounts of between 0.1 to 5% by weight (page 8, lines 3-30 and page 10, lines 3-6).

The prior art anticipates the instant claims insofar as it discloses a film forming composition comprised of hydroxypropyl cellulose and citric acid, malic acid or lactic acid in amounts of 0.1 to 5%.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eichel et al. (EP 0 391 518).

Eichel et al. is discussed above.

Eichel et al. does not each a specific embodiment wherein the non-gelatin film is additionally treated with a solution comprising one or more acids.

Eichel et al. does teach that the inner wall can contain acid and that the inner wall can be layered with acid; and that the release of drug is dependent on the amount of acid in either (column 4, lines 4-44). It would reasonably be expected that a wall comprised of the acid and a polymer would control the release of drug differently than a layer comprised of just acid, therefore combining the two would provide a release of the active based on the amount of acid in both the acid layer and the amount in the wall; the release of drug of the modified invention would be different than the release resulting from incorporating the acid in either the wall or the acid layer alone. Accordingly, it would have been obvious to prepare the inner wall comprised of acid and also include a layer of acid over the inner wall motivated by the desired to control or tailor drug release.

Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Signorino (WO 1992/11002) in view of Eichel et al. (EP 0 391 518).

Signorino and Eichel et al. are discussed above.

Signorino does not teach an acid comprising about 23% by weight.

Eichel et al. does not teach HPMC is the non-gelatin polymer.

At the time of the invention, it would have been obvious to modify the composition of Signorino to include from about 0-50% of acid of Eichel et al. motivated by the desired to control the delay time of the release of active ingredient as taught by Eichel et al.

It would have been obvious to modify the composition of Signorino to be comprised of two layers comprised of HPMC and an organic acid which are in turn separated by a layer of organic acid, motivated by the desire to control the rate of release of active agent through incorporation of an organic acid and since multi-layered capsules are an art recognized delivery system as taught by Eichel et al.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Signorino as applied to claims 1-9 above, and further in view of Nowak (WO 2002/03968).

Signorino is discussed above.

Signorino does not teach that the film is foamed, expanded or gasified.

Nowak teaches a delivery capsule comprising a thermoplastic film of foamed modified hydroxypropylmethyl cellulose. The foamed material dissolves rapidly in the

mouth of a consumer (Abstract). The presence of voids in the foamed film results in the film rapidly starting to dissolve in the mouth of a consumer (page 2, last paragraph). The foamed film provides a pleasant, melt-in-the-mouth sensation (page 3, 1st paragraph).

At the time of the invention, it would have been obvious to modify the composition of Signorino to include the foamed hydroxypropylmethyl cellulose of Nowak motivated by the desire to control the release of active in the mouth and to provide a pleasant, melt-in-the-mouth sensation to the consumer.

Double Patenting

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-25 of copending Application No. 11/999545 in view of Moing et al. (1997)

The claims of the copending application are drawn to hydroxypropylmethyl cellulose films comprising a fruit acid or salt thereof; and to delivery capsules comprised of said films.

Moing et al. teach that citric acid and malic acid are organic fruit acids known in the art.

Therefore, it would have been obvious to use the citric acid and malic acid of Moing in the compositions of the copending application as the organic acid, i.e. fruit acid, since both are well-known fruit acids.

This is a provisional obviousness-type double patenting rejection.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612